

REMARKS

Acceptance of the terminal disclaimer is noted with appreciation.

Rejected claims 37 and 41 have been cancelled without prejudice.

Claims 34, 42 and 64 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Goodwin et al '061 in view of Ianniruberto et al '890. This rejection is respectfully traversed with respect to these claims as amended herein.

Specifically, independent claims 34 and 64 variously recite “the dilating element having a smooth oval shaped exterior contour symmetrically disposed about the central axis to facilitate atraumatic expansion of tissue following dissection by the tapered distal tip advancing through tissue, the dilating element having a cross-sectional dimension of the oval shape that is greater than the cross-sectional dimension of the distal end of the cannula and greater than the cross-sectional dimension of the distal tip.”

In addition, the dependent claim is further limited by recitation of “the dilating element is compressible.”

These aspects of the claimed invention promote dissection and then dilation of tissue as the distal tip advances through tissue. And, the dilating element has a specified shape and increased cross-sectional dimension relative to the cross-sectional dimension of the distal tip.

These aspects of the claimed invention are not disclosed or fairly suggested by the disclosures of the cited references considered either alone or in the combination proposed by the Examiner. It must be noted that Goodwin et al '061 merely discloses a tissue-dissecting tip at the distal end of a cannula, with no hint or suggestion also of a tissue-dilating element positioned proximal of the distal tip. At best, this reference merely incorporates a pair of diametrically-oriented, blunt-edged blades 18 to facilitate tissue dissection (col. 4, lines 37-40), but is deficient of an additional element on the cannula for dilating the dissected tissue behind the advancing distal tip.

Nor does the trocar of Ianniruberto et al '890 'cure' the deficient disclosure of Goodwin et al '061. It must be noted that neither the lead screw 114 referenced by the Examiner, nor other elements of the apparatus disclosed by this reference, are positioned proximal to a tissue-dissecting distal tip then to dilate the dissected tissue. At best, this trocar merely serves as an entry port through skin, with the lead screw 114 referenced by the Examiner embedded in skin 400. There is thus no attachment mechanism between any dilating element and a supporting cannula that in any way resembles Applicants' claimed invention. This combination of references thus fails to establish even a *prima facie* basis, including *all* recited elements, from which a proper determination of obviousness may be formed.

Amended claims 34, 42 and 64 are therefore submitted to be patentable now over the cited art.

Rejected 46 and 50 have been cancelled without prejudice.

Claims 43 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Goodwin et al '061. This rejection is respectfully traversed with respect to this claim as amended herein.

Claim 43 specifically recites “dilating elements each adapted to mount on the cannula proximal to the distal tip, each dilating element having a smooth oval shaped exterior contour to facilitate atraumatic expansion of tissue following dissection by the tapered distal tip, each dilating element having a cross-sectional dimension of the oval shape that is greater than the cross-sectional dimension of the distal tip, the cross-sectional dimension of each dilating element being different from one another, each dilating element further comprising a mating lock adapted to mate with the locking mechanism on the cannula for removably positioning each dilating element on the cannula, wherein different dilating elements may be mounted one at a time on the cannula for dissecting tissue and therefore forming cavities of differing dimensions.”

These aspects of the claimed invention facilitate both dissection of tissue and dilation of the dissected tissue to form an expanded channel through tissue as both the tip and dilating element are advanced together through tissue.

These aspects of the claimed invention are not disclosed or even suggested by the cited reference that does not disclose any tissue dilator *in addition* to the tissue-dissecting tip. At best, this reference merely relies upon “blunt-edged blades 18, or tissue separator . . . to facilitate the penetration or *dissection* of tissue.” (Emphasis added)(Col. 4, lines 35-39). However, these blunt-edged blades are positioned on the tapered walls of the tip, with lateral dimensions not greater than the maximum diameter of the tip, and cannot therefore also serve as dilators to expand tissue dissected by the tip. At best, the attachment mechanism referenced by the Examiner merely secures the tip to the cannula, with no suggestion also of a dilating element positioned proximal the distal tip. It is therefore submitted that Goodwin et al ‘061 fails to establish even a *prima facie* basis, including *all* recited elements, from which a proper determination of obviousness may be formed. Claim 43 is therefore submitted to be patentably distinguishable over the cited art.

Claims 35 and 54 have been rejected as being unpatentable over Goodwin et al ‘061 in view of Ianniruberto et al ‘890. This rejection is respectfully traversed with respect to these claims as amended herein.

Specifically, dependent claim 35 is further limited by recitation of “the dilating element having a smooth oval shaped exterior contour symmetrically disposed about the central axis to facilitate atraumatic expansion of tissue following dissection by the tapered distal tip advancing through tissue , the dilating

element having a cross-sectional dimension of the oval shape that is greater than the cross-sectional dimension of the distal end of the cannula and greater than the cross-sectional dimension of the distal tip.” In addition, claim 54 specifically recites “a solid dilating element of fixed outer dimension removably mounted on the cannula proximal to the distal tip, the dilating element having a smooth oval shaped exterior contour to facilitate atraumatic expansion of tissue following dissection by the tapered distal tip, the dilating element having a cross-sectional dimension of the oval shape that is greater than the cross-sectional dimension of the distal end of the cannula and greater than the cross-sectional dimension of the distal tip.”

These aspects of the claimed invention establish a dilator element positioned proximal of the distal tip for dilating tissue that is dissected by the distal tip as the configuration advances through tissue together on a supporting cannula.

These aspects of the claimed invention are not disclosed or fairly suggested by the cited references considered either alone or in the combination proposed by the Examiner. Specifically, Goodwin et al ‘061 fails to disclose any structure proximal of the distal tip that constitutes a dilating element, and Ianniruberto et al ‘890 merely discloses a trocar with a screw-like tissue-gripping device 100 that embeds in the skin 400 about an entry incision to facilitate insertion therethrough of a cannula 350. At best, this combination of references which, if even possible to

combine without materially altering the purposes of these references, merely supports passing a cannula, such as disclosed by Goodwin et al '061, through the embedded trocar of Ianniruberto et al '890, without any hint or suggestion of an additional dilating element mounted proximal the distal tip on a supporting cannula for advancing together through tissue. It is therefore respectfully submitted that this combination of references fails to establish even a *prima facie* basis, including *all* recited elements, from which a proper determination of obviousness can be formed, and that claims 35 and 54 are patentably distinguishable over the cited art.

Claims 38-40 and 47-49 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Goodwin et al '061 in view of Ianniruberto et al '890. This rejection is respectfully traversed with respect to these claims as amended herein.

These dependent claims variously define an oval-shaped tissue-dilating element in addition to a tissue-dissecting distal tip, as detailed in the above Remarks, and are variously further limited by the defined spacer length and shape and size of the dilating element positioned on a cannula proximal the distal tip.

These aspects of the claimed invention are not disclosed or fairly suggested by the cited references considered either alone or in the combination proposed by the Examiner. And, contrary to the Examiner's analyses, neither one of these references nor their combination "teach" the claimed invention since neither

reference discloses a tissue-dilating element in addition to a tissue-dissecting distal tip mounted on a supporting cannula for advancing together through tissue. These references considered either alone or in combination therefore fail to disclose the specifically-recited elements in the defined structure of the Applicants' invention, and thus also fail to establish a *prima facie* basis from which a proper determination of obviousness can be formed. The dependent claims 38-40 and 47-49 are therefore submitted to be patentably distinguishable over the cited art.

Favorable reconsideration and allowance of all pending claims are solicited.

Respectfully submitted,
Albert K. Chin

By: /Albert C. Smith/

Dated: 12/10/08

Albert C. Smith, Reg. No.: 20,355
Fenwick & West LLP
801 California Street
Mountain View, CA 94041
Tel.: (650) 335-7296
Fax.: (650) 938-5200